Response Dated April 18, 2008

Response to Restriction Requirement dated March 28, 2008

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the

application:

**LISTING OF CLAIMS:** 

1. (withdrawn) A therapeutic composition for symptomatic treatment of respiratory

allergies in a warm-blooded animal, said composition comprising a pharmaceutically

effective amount of diphenhydramine tannate at a consistent purity in substantial absence of

an organic solvent and in solid dosage form.

2. (withdrawn) The composition of claim 1, wherein said organic solvent is an alcohol.

3. (withdrawn) The composition of claim 1, wherein said organic solvent is a mineral

oil.

4. (withdrawn) The composition of claim 1, wherein said organic solvent is isopropyl

alcohol.

5. (withdrawn) The composition of claim 1, wherein said organic solvent is glycerin.

6. (withdrawn) The composition of claim 1, wherein said organic solvent is propylene

glycol.

7. (withdrawn) The composition of claim 1, wherein said organic solvent is ethanol.

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8. (withdrawn) The composition of claim 1, further including at least one additional active ingredient selected from a group consisting of antihistamines, sympathomimetics, decongestants, cough suppressants, antitussives and expectorants.

9. (withdrawn) A therapeutic composition for symptomatic treatment of respiratory allergies in a warm-blooded animal, said composition comprising a pharmaceutically effective amount of diphenhydramine tannate at a consistent purity in substantial absence of decomposition products of diphenhydramine produced at temperatures above about 50 degrees C and in solid dosage form.

10. (withdrawn) The composition of claim 9 wherein said decomposition product is benzhydrol.

11. (withdrawn) The composition of claim 9 wherein said decomposition product is benzophenone.

- 12. (withdrawn) The composition of claim 9 wherein said decomposition product is diphenylchloromethane.
- 13. (withdrawn) The composition of claim 9 wherein said decomposition product is dimethylaminoethanol.
- 14. (withdrawn) The composition of claim 9 wherein said decomposition product is diphenylmethane.

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- 15. (withdrawn) The composition of claim 9 wherein said decomposition product is diphenyl alkyl ether.
- 16. (withdrawn) The composition of claim 9, further including at least one additional active ingredient selected from a group consisting of antihistamines, sympathomimetics, decongestants, cough suppressants, antitussives and expectorants.
- 17. (original) A therapeutic composition for symptomatic treatment of respiratory allergies in a warm-blooded animal, comprising a pharmaceutically effective amount of diphenhydramine tannate at a consistent purity prepared by:
- (a) dissolving the salt or free base of the diphenhydramine in a pharmaceutically acceptable liquid to form a solution at a maximum temperature and pH value, that does not cause decomposition of the active pharmaceutical ingredient;
  - (b) separately mixing an anti-clumping agent with tannic acid to generate a blend;
- (c) combining the solution from step (a), with the blend of step (b) to form a tannate salt of diphenhydramine;
- 10 (d) combining the tannate salt of the diphenhydramine of step (c) with a pharmaceutically acceptable excipient to form a granulate; and
  - (e) processing the granulate into a tablet, capsule or other solid dosage form.
- 18. (original) The composition of claim 17, further including at least one additional active ingredient selected from a group consisting of antihistamines, sympathomimetics, decongestants, cough suppressants, antitussives and expectorants.

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19. (withdrawn) A method for symptomatically treating respiratory allergies in a warm-blooded animal, comprising administering to said warm-blooded animal a pharmaceutically effective amount of diphenhydramine tannate at a consistent purity in substantial absence of an organic solvent and in solid dosage form.

- 20. (withdrawn) A method for symptomatically treating respiratory allergies in a warm-blooded animal, comprising administering to said warm-blooded animal a pharmaceutically effective amount of diphenhydramine tannate at a consistent purity in substantial absence of decomposition products of diphenhydramine produced at temperatures above about 50 degrees C and in solid dosage form.
- 21. (original) A method for symptomatically treating respiratory allergies in a warm-blooded animal, comprising administering to said warm-blooded animal a pharmaceutically effective amount of diphenhydramine tannate at a consistent purity prepared by:
- (a) dissolving the salt or free base of the diphenhydramine in a pharmaceutically acceptable liquid to form a solution at a maximum temperature and pH value, that does not cause decomposition of the active pharmaceutical ingredient;
  - (b) separately mixing an anti-clumping agent with tannic acid to generate a blend;
- (c) combining the solution from step (a), with the blend of step (b) to form a tannate salt of diphenhydramine;
- 10 (d) combining the tannate salt of the diphenhydramine of step (c) with a pharmaceutically acceptable excipient to form a granulate; and
  - (e) processing the granulate into a tablet, capsule or other solid dosage form.
- 22. (withdrawn) The composition of claim 1 in substantial absence of any other active ingredient.

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23. (withdrawn) The composition of claim 1 in substantial absence of any other tannate salt.

24. (withdrawn) The composition of claim 9 in substantial absence of any other active ingredient.

- 25. (withdrawn) The composition of claim 9 in substantial absence of any other tannate salt.
- 26. (original) The composition of claim 17 in substantial absence of any other active ingredient.
- 27. (original) The composition of claim 17 in substantial absence of any other tannate salt.